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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/393,302	HOVANESSIAN ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-24* is/are pending in the application.

4a) Of the above claim(s) *1,7,8,11,12 and 14-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4-6,9,10,13 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed on 10-7-2002 is acknowledged. Claims 2, 6 and 13 have been amended. Claim 3 has been canceled. Claim 24 has been added. Claims 2, 4-6, 9-10, 13 and 24 are currently under examination.

This application contains claims 1, 7-8, 11-12and 14-23 drawn to an invention non-elected with traverse in Paper No. 14. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

The corrected or substitute drawings were received on 10-7-2002. These drawings are accepted and have been forwarded to the draftsman.

Claim Objections Withdrawn

The objection to claims 3-6, 9-10 and 13 for being dependent on non-elected inventions is withdrawn.

Claim Rejections Withdrawn

The rejection of claim 13 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or use the

invention (therapeutic compositions comprising inhibitor molecules for prevention and/or treatment of AIDS) is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "peptidic or non-peptidic inhibitor molecule" is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "inhibitor is not nuclear nucleolin" is withdrawn in light of the amendment thereto.

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "able to" is withdrawn in light of the amendment thereto.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by its recitation of various amino acid positions of SEQ ID NO:1 is withdrawn in light of the amendment thereto.

The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "peptide fragment" is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "pseudopeptide counterpart" is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by reciting improper Markush language is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by reciting improper Markush language is withdrawn in light of the amendment thereto.

The rejection of claims 2-4, 6, 10 and 13 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suzuki et al. (Biochemical Journal, Vol. 289 Part 1, pages 109-115, January 1, 1993) is withdrawn in light of the amendment thereto and the cancellation of claim 3. It should be noted that the amendment is deemed to constitute new matter and hence this rejection may be reinstated.

The rejection of claims 2-4, 6, 9-10 and 13 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sapp et al. (European Journal of Biochemistry, Vol. 179 No. 3, pages 541-548, February 15, 1989) is withdrawn in light of the amendment thereto and the cancellation of claim 3. It should be noted that the amendment is deemed to constitute new matter and hence this rejection may be reinstated.

Claim Objections

The objection to the specification for failing to comply with 37 C.F.R. 1.821(d) is maintained for reasons of record. As of May 3, 2001 corrections to drawings cannot be held in abeyance. The newly submitted drawings were insufficient to overcome the objection (see PTO form 948, attached).

Claims 6, 9-10, 13 and 24 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections Maintained and New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4-6, 9-10, 13 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 2 to recite, "fragment of **extracellular or cytoplasmic** P95/nucleolin ..." This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. The specification discloses P95/nucleolin without any description as to its location within the cell. Therefore, the limitation "**extracellular or cytoplasmic** P95/nucleolin " is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-6, 9-10, 13 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rendered vague and indefinite by the use of the term "alters and/or prevents". It is unclear what is meant by said term. What constitutes an alteration? Isn't "prevention" considered to be an "alteration"?

Claim 2 is rendered vague and indefinite by the use of the term "peptidic fragment" alters and/or prevents". It is unclear what is meant by said term. How does a "peptidic fragment" differ from other types of fragments? What constitutes a fragment? Two amino acids? 10 amino acids? Does said fragment need to posses a given function in order to meet the limitations of the claim?

Claim 2 is rendered vague and indefinite by the use of the term "homologous". It is unclear what is meant by said term. What is the basis for determining homology? Structure? Function? Some other criteria?

Claim 2 is rendered vague and indefinite by reciting improper Markush language. The listing of the members of the Markush group contains both conjunctions "or" and "and". It is suggested that the phrase "wherein the inhibitor is selected from the group consisting of a) a peptidic fragment of extracellular P95/nucleolin, b) a peptidic fragment of cytoplasmic P95/nucleolin, c) a peptidic fragment of P40/PHAPII, d) a peptidic fragment of P30/PHAPI, e) a pseudopeptide homologous to a peptide fragment of extracellular P95/nucleolin, f) a pseudopeptide homologous to a peptide fragment of cytoplasmic P95/nucleolin, g) a pseudopeptide homologous to a peptide fragment of P40/PHAPII and h) a pseudopeptide homologous to a peptide fragment of P40/PHAPI."

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "pseudopeptide which is homologous" is maintained for reasons of record. Applicant argues said term is described on page 16 of the specification.

Applicant's arguments have been fully considered and deemed non-persuasive since the passage cited by Applicant does not define said phrase.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The instant invention is drawn to various fragments of nucleolin that function to inhibit the interaction between gp120 of the HIV retroviruses and the V3 loop.

Claims 2, 4, 6, 9-10, 13 and 24 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Callebaut et al. (Virology Vol. 218, No. 1, pages 181-192, 1996) for the reasons outlined in the previous Office action in the rejection of claims .2-4, 6, 9-10 and 13.

Applicant argues:

1. Callebaut et al. only discusses the TASP pseudopeptide.

2. Callebaut et al. do not teach or suggest the use of peptidic fragments of extracellular or cytoplasmic nucleolin or psuedopeptides homologous to them.

3. Applicant does not claim the TASP pseudopeptide taught by Callebaut.

Applicant's arguments have been fully considered and deemed non-persuasive. The TASP pseudopeptide is encompassed by the instant invention since it is a pseudopeptide with that has a function homologous to P95 nucleolin and/or a fragment thereof.

35 USC § 103

Claims 2, 4-6, 9-10, 13 and 24 are rejected under 35 U.S.C. 103(a) as obvious over Srivastava et al. (FEBS Letters, Vol. 250, No. 1, pages 99-105, 1989) for the reasons outlined in the previous Office action in the rejection of claims .2-6, 9-10 and 13.

Applicant argues:

1. The amended claims read on extracellular or cytoplasmic nucleolin, not the nuclear nucleolin described in the cited reference.

Applicant's arguments have been fully considered and deemed non-persuasive. Srivastava et al. disclose the cDNA of human nucleolin. Since the bovine probes used were derived from the total RNA of the adrenal medulla, all forms of nucleolin would be utilized (see materials and methods section). As outlined previously, Srivastava et al. disclose the complete nucleotide and amino acid sequence for human nucleolin (see page 101). Srivastava et al. further disclose a comparison between nucleolin from humans, chickens and hamsters. Since the entire nucleolin protein was incorporated in the cDNA library (see page 109), in absence of evidence to the contrary, said library would generate all of the peptides/fragments of the claimed invention. While Srivastava et al. do not specifically describe the using said peptides/fragments for the inhibition of ph120/nucleolin binding, it would be an inherent property of said fragments. Determination of biological/chemical properties of each peptide/fragment would have been obvious to one of ordinary skill in the art since it constitutes a standard laboratory practice. Additionally, since Srivastava et al. knew the sequences of the cDNA fragments (see page 109), it would have been obvious to one of ordinary skill in the art to modify said sequences in order to enhance the stability etc of said peptide. One would have been motivated to make such modifications in order to protect said peptides from endogenous protease thus increasing the half-life of said peptides.

Claims 2, 4-6, 9-10, 13 and 24 are rejected under 35 U.S.C. 103(a) as obvious over Rankin et al. (Nucleic Acids Research, Vol. 21 No. 1, page 169) for the reasons outlined in the previous Office action in the rejection of claims .2-6, 9-10 and 13.

Applicant argues:

1. Rankin et al. teaches that nucleolin is a nucleolar specific protein that assists in the process of pre-ribosomal RNA as the ribosomes are assembled.

2. The amended claims read on extracellular or cytoplasmic nucleolin, not the nuclear nucleolin described in the cited reference.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, Rankin does not, contrary to Applicant's assertion, teach that nucleolin is a nucleolar specific protein that assists in the process of pre-ribosomal RNA as the ribosomes are assembled. Rankin et al. merely speculate on a possible function of nucleolin.

With regard to Point 2, Rankin et al. do not disclose the source of the nucleolin used to determine the cDNA sequence as being nuclear. In fact, Rankin et al. disclose that the cDNA sequence was constructed from "overlapping sequences recovered from an ovary cDNA library". This would indicate that the library was constructed using total RNA was used instead of only nuclear RNA.

As outlined in the previous Office action, Rankin et al. disclose the fully-length cDNA sequence of nucleolin. Rankin et al. differ from the instant invention in that they do not disclose specific peptides. However, it would have been obvious to one of ordinary skill in the art to use the disclosed cDNA sequence to produce polypeptides since it is standard laboratory practice to determine the functions of various sequences etc. Additionally, the cited reference reads on all the rejected claims since said claims recite open claim language.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 608-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LFS

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
December 24, 2002